EXPRESS MAIL NO.: EV380370164US

DATE MAILED: October 28, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Paul R. Hinton, et al.

Appl. No.: 10/687,118

Filed: October 15, 2003

For: ALTERATION OF FcRn BINDING AFFINITIES OR SERUM HALF-LIVES

OF ANTIBODIES BY MUTAGENESIS

Art Unit: 1653

Confirmation No. 2275

Examiner: Not Yet Assigned

Atty. Docket: 05882.0039.NPUS04

Information Disclosure Statement

Mail Stop Amendments Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

Applicant: Hinton, et al. Appl. No. 10/687,118

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
 - □ a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
 - □ b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - c. Before the mailing date of a first Office Action on the merits;
 - □ d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

or;

- □ 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
 - □ a. I hereby state that each item of information contained in this Information

 Disclosure Statement was first cited in any communication from a

 foreign patent office in a counterpart foreign application not more
 than three months prior to the filing of this Information Disclosure

 Statement. 37 C.F.R. § 1.97(e)(1), or
 - □ b. I hereby state that no item of information in this Information Disclosure

 Statement was cited in a communication from a foreign patent

office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or

□ c.	Attached is our Check No.	in the amount of \$	in
	payment of the fee under 37 C	C.F.R. § 1.17(p).	

- □ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i), and
 - □ a. I hereby state that each item of information contained in this Information

 Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - □ b. I hereby state that no item of information in this Information Disclosure

 Statement was cited in a communication from a foreign patent
 office in a counterpart foreign application, and, to my knowledge
 after making reasonable inquiry, no item of information contained
 in this Information Disclosure Statement was known to any
 individual designated in 37 C.F.R. § 1.56(c) more than three
 months prior to the filing of this Information Disclosure Statement.

 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.

Applicant: Hinton, et al. Appl. No. 10/687,118

□ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information. □ 6. A concise explanation of the relevance of the non-English language document(s) appears below: □ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. , filed , which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination. Copies of the documents were cited by or submitted to the Office in Application □ 8. No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing

Respectfully submitted,

Date: October 28, 2004

docket number 05882.0039.NPUS04.

Adam K. Whiting (Reg. No. 44,400)

HOWREY SIMON ARNOLD & WHITE, LLP 2941 Fairview Park Drive Box 7 Falls Church, VA 2204201 (650) 463-8133



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

PTO FORM 1449

APPLICATION NO. 10/687,118		
GROUP Not yet assigned		

			U.S. PAT	ENT DOCUMENTS					
*EXAMINER		DOCUMENT NUMBER	DATE	NAME	CLASS	s	UBCLASS	FILING D	
	1.	5,994,514	08/14/91						
	2.	20010033842A1	08/14/91						
	3.	6,165,745	04/24/92						
	4.	20030044858A1	05/07/92						_
	5.	20030003098A1	04/05/95						
	6.	20020098193A1	03/03/97						
	7.	6,277,375	08/21/01						
	8.	6,528,624	03/04/03						
·	9.	5,530,101	06/25/96						
	10.	5,834,597	11/10/98						
			FOREIGN PA	TENT DOCUMENTS		***************************************	•		
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY		CLASS	SUBCLASS		T
	11.	WO9304173A1	08/14/91	PCT				YES	NC
	12.	EP1260521A2	08/14/91	Europe		-			
	13.	WO9631229A1	04/05/95	РСТ					
	14.	WO9728267A1	02/02/96	РСТ	-		-		
	15.	WO9734631A1	03/18/96	РСТ					
	16.	WO9805787A1	08/02/96	PCT				1	
	17.	WO9847531A2	04/21/97	PCT					
	18.	WO0047625A2	02/12/99	PCT					
	19.	WO0158957A2	02/11/00	PCT					
	20.	WO0260919A2	12/12/00	PCT					
	21.	WO9902709A1	07/10/97	PCT					T
	22.	WO0042072A2	01/15/99	РСТ				 	\vdash

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) PTO FORM 1449 ATTY. DOCKET NO. 05882.0039.NPUS04 APPLICATION NO. 10/687,118 APPLICATION NO. 10/687,118

23.	WO9734621A1	09/25/97	РСТ				
24.	WO9958572A1	11/18/99	РСТ				
25.	WO9823289A1	06/04/98	PCT				
26.	WO9951642	10/14/99	РСТ				
	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)						
27.	Achatz, et al., "The IgE Int. Arch. Allergy Immu		eptor: a Key Regulator for the 31-4 (2001)	Productio	n of IgE An	tibodies	,"
28.			o acid mutation on the activa				
29.			bstitution abolishes the hetero	ogeneity o	f chimeric	-	
30.	Armour, et al., "Recombinant human IgG molecules lacking Fcgamma receptor I binding and monocyte triggering activities," Eur J Immunol, 29(8): 2613-24 (1999)						
31.	Armour, et al., "The Contrasting IgG-Binding Interactions of Human and Herpes Simplex Virus Fc Receptors," Biochem Soc. Trans., 30(4): 495-500 (2002)						
32.	32. Arya, et al. "Mapping of amino acid residues in the C mu 3 domain of mouse IgM important in macromolecular assembly and complement-dependent cytolysis," <i>J Immunol</i> 152(3): 1206-12 (1994)						
33.	Batra, et al., "Insertion of Constant Region Domains of Human IgG1 into CD4-PE40 Increases Its Plasma Half-Life," Molec. Immunol. 30(4), 379-386 (1993).			Its			
34.	34. Brekke, et al., "Human IgG isotype-specific amino acid residues affecting complement-mediated cell lysis and phagocytosis," Eur J Immunol 24(10): 2542-7 (1994)			d			
35.	Burmeister et al., "Crystal structure of the complex of rat neonatal Fc receptor with Fc," <i>Nature</i> 372:379-383 (1994).						
36.	Canfield, "The binding affinity of human IgG for its high affinity Fc receptor is determined by multiple amino acids in the CH2 domain and is modulated by the hinge region," <i>J Exp Med</i> 173(6): 1483-91 (1991)			(6):			
37.	Caron, et al., "Engineer Med 176(4): 1191-5 (19		I dimeric forms of IgG are mo	re effectiv	e antibodie	s," <i>J Ex</i>	p
38.	Chapman, et al., "Chara Receptor and Immunog	ecterization of lobulin G.," <i>J</i> .	the Interaction Between the Biol. Chem. 274(11): 6911-9	Herpes Sir (1999)	nplex Virus	Type 1	Fc
39.	Chappel, et al., "Identific	cation of a sec	condary Fc gamma RI binding	site withi	n a genetic	ally	

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) PTO FORM 1449 APPLICANT Paul R. Hinton, et al. FILING DATE 10/15/03 APPLICATION NO. 10/687,118 APPLICANT Paul R. Hinton, et al. FILING DATE 10/15/03 Not yet assigned

_	
	engineered human IgG antibody," J Biol Chem 268(33): 25124-31 (1993)
40.	Chaudhury et al., "The Major Histocompatibility Complex-related Fc Receptor for IgG (FcRn) Binds Albumin and Prolongs Its Lifespan," J. Exp. Med. 197(3), 315-322 (Feb. 3, 2003).
41.	Cole, et al., "Human IgG2 variants of chimeric anti-CD3 are nonmitogenic to T cells," J Immunol 159(7): 3613-21 (1997)
42.	Cole, et at., "HuM291, A Humanized Anti-CD3 Antibody, is Immunosuppressive to T Cells While Exhibiting Reduced Mitogenicity in Vitro," <i>Transplantation</i> , 68(4): 563-71 (1999)
43.	Dall'Acqua, et al., "Increasing the Affinity of a Human IgG1 for the Neonatal Fc Receptor: Biological Consequences," J. Immunol. 169(9): 5171-80 (2002)
44.	Deisenhofer, "Crystallographic refinement and atomic models of a human Fc fragment and its complex with fragment B of protein A from Staphylococcus aureus at 2.9- and 2.8-A resolution," Biochemistry 20:2361-2370 (1981)
45.	Delano, et al., "Convergent Solutions to Binding at a Protein-Protein Interface," Science, 287(5456): 1279-83 (2000)
46.	Dorai, et al., "Role of inter-heavy and light chain disulfide bonds in the effector functions of human immunoglobulin IgG1," Mol Immunol 29(12): 1487-91 (1992)
47.	Duncan, et al., "The binding site for C1q on IgG," Nature 332(6166): 738-40 (1988)
48.	Ehrlich et al., "Characterization of human monoclonal antibodies directed against hepatitis B surface antigen," <i>Hum. Antibodies Hybridomas</i> 3:2-7 (1992)
49.	El-Amine, et al., "In Vivo Induction of Tolerance by an Ig Peptide is not Affected by the Deletion of FcR or a Mutated IgG Fc Fragment," Int. Immunol, 14(7): 761-6 (2002)
50.	Firan, et al., "The MHC Class I-Related Receptor FcRn, Plays an Essential Role in the Matermofetal Transfer of Gamma-Globulin in Humans," Int. Immunol., 13(8): 993-1002 (2001)
51.	Ghetie and Ward, "Multiple roles for the major histocompatibility complex class I- related receptor FcRn," Annu. Rev. Immunol. 18:739-766 (2000)
52.	Ghetie et al., "Increasing the serum persistence of an IgG fragment by random mutagenesis," <i>Nat. Biotechnol.</i> 15:637-640 (1997)
53.	Helm, et al., "Identification of the high affinity receptor binding region in human immunoglobulin E," J Biol Chem 271(13): 7494-500 (1996)
54.	Hezareh, et al., "Effector Function Activities of a Panel of Mutants of a Broadly Neutralizing Antibody Against Human Immunodeficiency Virus Type," J. Virol., 75(24): 12161-8 (2001)
55.	Hinton et al., "Engineered Human IgG Antibodies with Longer Serum Half-lives in Primate," J. Biol. Chem. 279(8) 6213-6216 (2004).
56.	Homick, et al., "Single Amino Acid Substitution in the Fc Region of Chimeric TNT-3 Antibody Accelerates Clearance and Improves Immunoscintigraphy of Solid Tumors," J. Nucl. Med. 41(2):

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) PTO FORM 1449 ATTY. DOCKET NO. 05882.0039.NPUS04 APPLICATION NO. 10/687,118 APPLICATION NO. 10/687,118

	355-62 (2000)
57.	Isaacs, et al., "Therapy with monoclonal antibodies. II. The contribution of Fc gamma receptor binding and the influence of C(H)1 and C(H)3 domains on in vivo effector function," <i>J Immunol</i> 161(8): 3862-9 (1998)
58.	Ito, et al., "[An amino acid substitution determining G1m(x) allotypic marker]," Nippon Hoigaku Zasshi 43(2): 155-60 (1989)
59.	Jendeberg, et al., "Engineering of Fc(1) and Fc(3) from human immunoglobulin G to analyse subclass specificity for staphylococcal protein A," J Immunol Methods 201(1): 25-34 (1997)
60.	Jollife, "Humanized antibodies: enhancing therapeutic utility through antibody engineering," Int Rev Immunol 10(2-3): 241-50 (1993)
61.	Kim et al., "Mapping the site on human IgG for binding of the MHC class I-related receptor, FcRn," <i>Eur. J. Immunol.</i> 29:2819-2825 (1999).
62.	Kim et al., "Catabolism of the Murine IgG1 Molecule: Evidence that Both CH2-CH3 Domain Interfaces are Required for Persistence of IgG1 in the Circulation of Mice," <i>Scand. J. Immunol.</i> 40, 457-465 (1994)
63.	Kim, et al., "Localization of the site of the murine IgG1 molecule that is involved in binding to the murine intestinal Fc receptor," Eur J Immunol 24(10): 2429-34 (1994)
64.	Kostelny et al., "Humanization and characterization of the anti-HLA-DR antibody 1D10," Int. J. Cancer 93:556-565 (2001)
65.	Lund, et al., "Human Fc gamma RI and Fc gamma RII interact with distinct but overlapping sites on human IgG," J Immunol 147(8): 2657-62 (1991)
66.	Lund, et al., "Multiple binding sites on the CH2 domain of IgG for mouse Fc gamma R11," Mol Immunol 29(1): 53-9 (1992)
67.	Lund, et al., "Multiple interactions of IgG with its core oligosaccharide can modulate recognition by complement and human Fc gamma receptor I and influence the synthesis of its oligosaccharide chains," J Immunol 157(11): 4963-9 (1996)
68.	Martin et al., "Crystal structure at 2.8 A of an FcRn/heterodimeric Fc complex: mechanism of pH-dependent binding," <i>Mol. Cell</i> 7:867-877 (2001)
69.	Martin, W.L. "Protein-Protein Recognition: The Neonatal Fc Receptor and Immunoglobulin G," Doctoral dissertation, California Institute of Technology (2001)
70.	McDonnell, et al., "The Structure of the IgE Cepsilon2 Domain and its Role in Stabilizing the Complex with its High-Affinity Receptor FcepsilonRlalpha," Nat. Struc. Biol., 8(5): 437-41 (2001)
71.	Medesan et al., "Comparative studies of rat IgG to further delineate the Fc:FcRn interaction site," Eur. J. Immunol., 28:2092-2100 (1998)
72.	Medesan, et al., "Delineation of the amino acid residues involved in transcytosis and catabolism of

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) PTO FORM 1449 ATTY. DOCKET NO. 05882.0039.NPUS04 APPLICANT Paul R. Hinton, et al. FILING DATE 10/15/03 APPLICANT Paul R. Hinton, et al. FILING DATE 10/15/03 APPLICATION NO. 10/687,118

	mouse IgG1," <i>J Immunol</i> 158(5): 2211-7 (1997)
73.	Morrison, et al., "Sequences in Antibody Molecules Important for Receptor-Mediated Transport Into the Chicken Egg Yolk," Mol. Immunol 38(8): 619-25 (2002)
74.	Muraoka, "Structural requirements for IgM assembly and cytolytic activity. Effects of mutations in the oligosaccharide acceptor site at Asn402," <i>J Immunol</i> 142(2): 695-701 (1989)
75.	Nagaoka, et al., "Single Amino Acid Substitution in the Mouse IgG1 Fc region induces drastic enhancement of the Affinity to Protein A," <i>Protein Eng.</i> , 16(4): 243-5 (2003)
76.	Newman, et al., "Modification of the Fc Region of a Primatized IgG Antibody to Human CD4 Retains its Ability to Modulate CD4 Receptors But Does Not Deplete CD4(+) T Cells in Chimpanzees," Clin. Immunol. 98(2): 164-74 (2001)
77.	Popov, et al., "The stoichiometry and affinity of the interaction of murine Fc fragments with the MHC class I-related receptor, FcRn," Mol Immunol 33(6): 521-30 (1996)
78.	Radaev, et al., "Recognition of Immunoglobulins by Fc gamma Receptors," Mol. Immunol. 38(14): 1073-83 (2001)
79.	Raghavan et al., "Investigation of the interaction between the class I MHC-related Fc receptor and its immunoglobulin G ligand," <i>Immunity</i> 1:303-315 (1994)
80.	Raghavan, et al., "Analysis of the pH dependence of the neonatal Fc receptor/immunoglobulin G interaction using antibody and receptor variants," <i>Biochemistry</i> 34(45): 14649-57 (1995)
81.	Saper et al., "Refined structure of the human histocompatibility antigen HLA-A2 at 2.6 A resolution," <i>J. Mol. Biol.</i> 219:277-319 (1991)
82.	Sarmay, et al., "Mapping and comparison of the interaction sites on the Fc region of IgG responsible for triggering antibody dependent cellular cytotoxicity (ADCC) through different types of human Fc gamma receptor," Mol Immunol 29(5): 633-9 (1992)
83.	Shields et al., "High resolution mapping of the binding site on human IgG1 for Fc gamma RI, Fc gamma RII, Fc gamma RII, and FcRn and design of IgG1 variants with improved binding to the Fc gamma R," <i>J. Biol. Chem.</i> 276:6591-6604 (2001)
84.	Shopes, "A genetically engineered human IgG mutant with enhanced cytolytic activity," <i>J Immunol</i> 148(9): 2918-22 (1992)
85.	Simister and Mostov, "An Fc receptor structurally related to MHC class I antigens," <i>Nature</i> 337:184-187 (1989)
86.	Tao, "Studies of aglycosylated chimeric mouse-human IgG. Role of carbohydrate in the structure and effector functions mediated by the human IgG constant region," <i>J Immunol</i> 143(8): 2595-601 (1989)
87.	Taylor, et al., "In Vitro and in Vivo Activities of OX40 (CD134)-IgG Fusion Protein Isoforms with Different Levels of Immune-Effector Functions," J. Leukoc. Biol., 72(3): 522-9 (2002)

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO. APPLICATION NO. 10/687,118		
PTO FORM 1449	APPLICANT Paul R. Hinton, et al.		
	FILING DATE 10/15/03	GROUP Not yet assigned	

 88.	Ward and Ghetie, "The effector functions of immunoglobulins: implications for therapy," <i>Ther. Immunol.</i> 2:77-94 (1995)
89.	Ward et al., "Evidence to Support the Cellular Mechanism Involved in Serum IgG Homeostasis in Humans," Int'l Immunol. 15(2), 187-195 (2003).
90.	Wawrzynczak, et al., "Recombinant mouse monoclonal antibodies with single amino acid substitutions affecting Clq and high affinity Fc receptor binding have identical serum half-lives in the BALB/c mouse," Mol Immunol 29(2): 221-7 (1992)
91.	Weng et al., "Computational determination of the structure of rat Fc bound to the neonatal Fc receptor," <i>J. Mol. Biol.</i> 282:217-225 (1998)
92.	West and Bjorkman, "Crystal structure and immunoglobulin G binding properties of the human major histocompatibility complex-related Fc receptor," <i>Biochemistry</i> 29:9698-9708 (2000)